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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,724	01/03/2001	Masafumi Kitakaze	58777.000003	1212

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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/752,724	KITAKAZE, MASAFUMI	
	Examiner	Art Unit	
	Rita Mitra	1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *16 July 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *6-16*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *PTO 892 with reference*

Continuation Sheet (PTO-303), item 5.

The Amendment and Response filed on June 15, 2004 has been received. Claims 1-5 have been cancelled. Claims 6-16 are pending. The following grounds of rejection are, or remain, applicable to the pending claims.

In regard to the rejection of claims 6-16 under 35 U.S.C. 102(b) as being anticipated by Takata et al. (Cardiovascular Research, 32, 286-293, 1996), Applicants traverse the rejection. The traversal is on the ground of Takata et al. teaches a pharmaceutical composition provides no basis for rejection of claims 6-16 which are directed to methods.

In response Applicants' attention is drawn to the office action of January 16, 2004 where it was stated that Takata et al. teach a pharmaceutical composition that comprises an effective amount of synthetic alpha human ANP (atrial natriuretic peptide), which increases the level of cyclic guanosine monophosphate (cGMP), and has cardioprotective effects on myocardial ischemia and reperfusion injury (see abstract; page 287, col 1, lines 12-14 and 24-25; page 289, col 1, lines 35-39; Fig. 1 and Table 1). Takata et al. **also teach a method of cardioprotection** (claim 6) of myocardial ischemia (claims 8) and reperfusion injury (7) by administering a composition comprising an effective amount of synthetic alpha human ANP (atrial natriuretic peptide) (claim 6, 9 and 10), which increases the level of cyclic guanosine monophosphate (cGMP) (claim 6), and has cardioprotective effects on myocardial ischemia and reperfusion injury (claims 6, 7, 8), (see abstract; page 287, col 1, lines 12-14 and 24-25, col 2, lines 14-18; page 289, col 1, lines 35-39; Fig. 1 and Table 1). Therefore, Takata's method anticipates claims 6-10 of instant application.

In addition it should also be noted that in previous office action in response to Applicants arguments that Takata et al. explicitly teaches away from treating an infarct region by instead disclosing and teaching methods of preventing the myocardial ischemic event from even occurring, it was stated that arguments are not found persuasive because

the instant claims recite "prophylaxis" which is the same as "prevention" described in Takata reference. Therefore rejection of claims 6-16 under 102(b) was maintained.

In response to Applicants arguments in the current amendments (pages 4-6) it should be noted that the rejection is on the basis of inherency. Takata et al. teach a method of cardioprotection of myocardial ischemia and reperfusion injury by administering a composition comprising an effective amount of synthetic alpha human ANP, which increases the level of cGMP, and has cardioprotective effects on myocardial ischemia and reperfusion injury. Thus, Takata et al reference discloses all the elements of the claim expressly except the element "reducing an infarct region," which is inherent in the disclosure. Such a reference is still anticipatory (see Feit et al. 2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21).

Feit et al. teach three criteria for inherency. (1) The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily **results** in the claimed process as opposed to a **possibility.** (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. 3) The third criterion is the legal standard. Feit et al., citing *Continental Can,* state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing.

The above criteria required for establishing the inherency are satisfied in Takata reference. In general infarction is a cause of ischemia and reperfusion injury. Takata et al.'s method protects the myocardial ischemia and reperfusion injury by administering ANP, therefore, it would also have an effect on the infarction caused by the ischemia and reperfusion injury as claimed in the current invention, thus establishes criterion 1. The practice of Takata's method will result to an effect on the size of the infarction, thus establishes criterion 2. It is art recognized that ischemic heart disease causes an infarction on the cardiac muscles and the size of the infarction can be reduced by using substances like thrombolytic agents. Therefore, the element "reducing an infarct region" of the

claim, which is inherent in Takata's reference would be recognized by persons of ordinary skill, thus establishing criterion 3. Therefore rejection of claims 6-16 under 102(b) is maintained.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (571) 272-0925. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette,1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.

Rita Mitra, Ph.D.
August 26, 2004

Jon P. Weber, Ph.D.
Primary Examiner